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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,242	06/23/2006	Yusuke Murakawa	084437-0169	1685

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EXAMINER	
DICKINSON, PAUL W	

ART UNIT	PAPER NUMBER
1618	

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09/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,242	MURAKAWA ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,6 and 22-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,6 and 22-34* is/are rejected.

7)☒ Claim(s) *22-24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/14/2009 has been entered.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

New Grounds of Rejection

Claim Objections

Claims 22-24 objected to because of the following informalities: The phrase "wherein the product has the characteristics of an angle of repose of... " is grammatically incorrect. "Characteristics" and "an angle of repose of..." need to agree in plurality. The phrase should read "wherein the product has the characteristic of an angle of repose of...". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-6 and 22-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites "the weight ratio of the compound and the surfactant is 1: about 0.001 to less than 0.1". It is unclear what this ratio means. It could be interpreted as (1:about 0.001) to less than 0.1. It could be interpreted as 1:(about 0.001 to less than 0.1). Additionally, it is unclear what values are encompassed by "about 0.001 to less than 0.1". There are two problems with this range: (1) Less than 0.1 is a maximum that encompasses all values below 0.1, while about 0.001 to 0.1 encompasses values between about 0.001 to 0.1. (2) It is unclear if "about" qualifies only to 0.001 or to the range as a whole (i.e. "(about 0.001) to less than 0.1" or "about (0.001 to less than 0.1)"). Claims 6 and 22-34 do not clarify the above and are indefinite for the same reason.

Claim 6 recites "wherein the weight ratio is 1: about 0.005 to about 0.05". It is unclear if this should be read "(1: about 0.005) to about 0.05" or "1: (about 0.005 to about 0.05).

Claims 22-25 recite "wherein the product has the characteristics of an angle of repose of...". The specification at page 7, lines 15-26 states that the angle of repose of the granulated product is measured by the following method: "Specifically, 20 g of granulate product is supplied from the upper funnel using a powder tester... and is subjected to moderate vibration by means of a vibrator, causing the granulated product to be dropped. After the powders dropped

completely, the angle between the powder layer and the horizontal surface is referred to as an angle of repose". The meaning of "angle of repose" understood in light of the specification is unclear for the following two reasons: (1) Does the experiment by definition require 20 g of the granulated product, or is 20 g merely illustrative. (2) It is unclear what the "powder layer" is. Is this the vertical (near vertical) stream of granules flowing from the stem of the funnel? Is the funnel held at 90° from the horizontal surface?

Claim 25 recites "wherein the weight ratio of additives other than the surfactant..." . It is unclear what additives are encompassed by "additives other than the surfactant". Is the "compound with poor wettability" of claim 5 considered an "additive other than the surfactant"? Claim 5 is open to additional ingredients, including additional surfactants other than the surfactant that is present in a compound:surfactant ratio of 1:about 0.001 to less than 0.1. If other surfactants are present, are these included in "additives other than the surfactant"?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 5-6 and 22-33 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 02056881 (WO '881; US 20040115264 is an English equivalent). WO '811 discloses a granulated product comprising 3.4 kg fenofibrate and 119 g polysorbate 80 (a surfactant) (see Example 2). Fenofibrate is a hydrophobic compound and corresponds to a compound with poor wettability according to the instant specification (see instant specification: page 4, line 19 to page 5, line 1). The ratio of 3.4 kg (3400 g) fenofibrate to 119 g polysorbate 80 is equivalent to 1:0.035, which anticipates the ratios of instant claims 5-6. There is also 1.156 kg pregelatinized starch, 0.595 kg microcrystalline cellulose, 178.5 g polyvinylpyrrolidone present in the granules. These additives comprise 35 wt% of the granulated product (calculated from (1156 g + 595 g + 178.5 g)/(3400 g + 1156 g + 595 g + 178.5 g + 119 g) x 100%) which anticipates the range of instant claim 25. Further in Example 2, polyvinylpyrrolidone (a binder) is present in 5.2 wt% relative to fenofibrate (calculated from 178.5 g/3400 g x 100%) which anticipates the range of instant claim 26.

WO '811 does not disclose the angle of repose of the granulated product. A composition cannot, however, be separated from its properties, and the granulated product of WO '811 is structurally identical to the claimed granulated

formulation. Based on the substantially identical process using identical components, the Examiner has a reasonable basis to believe that the properties claimed in the present invention are inherent in the granulated product of WO '811. ""[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)." MPEP § 2112, I.

The granulated product of WO '811 is tableted (see Example 2). The tablet is a molded product, and anticipates instant claims 27-33.

Claims 5-6, 22-26 and 34 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by US 6660296 ('296). '296 discloses a granulated product comprising diltiazem and a surfactant, wherein the ratio of diltiazem and the surfactant is 98:2 (see abstract; claims 1 and 11-12). Diltiazem is sparingly soluble (see col 1, lines 24-30) and corresponds to a compound with poor wettability according to the instant specification (see instant specification page 4, line 19 to page 5, line 1). The weight ratio 98:2 is equivalent to 1:0.02. This ratio anticipates the ranges of instant claims 5-6. Aside from diltiazem and surfactant, there is also be a neutral granular support present in 20-25 wt%, a binder present

in 0.5-10 wt%, and a plasticizer present in 0-5 wt% (see col 3, lines 30-40). If the minimum of each of these additives is added, this corresponds to 20.5 wt% of the formulation (calculated from 20 wt% + 0.5 wt%+ 0 wt%). If the maximum of each of these additives is added, this corresponds to 40 wt% (calculated from 25 wt% + 10 wt% + 5 wt%). Thus the additives may be present from 20.5 wt% to 40 wt%, which anticipates the range about 20 wt% to 60 wt% of instant claim 25. In this same formulation, the diltiazem may be present from 70-75%. Accordingly, the weight ratio of the binder with respect to diltiazem may be 0.5/70, or 1 wt%. This anticipates the range about 2 to about 5 wt% of instant claim 26. Regarding instant claim 34, the particles of the granular formulation have an average diameter of between 0.4 and 0.9 mm, and it is reasonable that most of these particles (at least 35% by weight) would not pass through a 100-mesh sieve, which has a sieve size of 0.152 mm. The rationale for this is that the smallest average particle size is at least 2.5 times larger than the sieve size (calculated from 0.4/0.152), and the largest average particle size is nearly 6 times larger (calculated from 0.9/0.152). The majority of these relatively large particles would not pass through a 100-mesh sieve.

'296 does not disclose the angle of repose of the granulated formulation. A composition cannot, however, be separated from its properties, and the granulated product of '296 is structurally identical to the claimed granulated formulation. Based on the substantially identical process using identical components, the Examiner has a reasonable basis to believe that the properties claimed in the present invention are inherent in the granulated product of '296.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)." MPEP § 2112, I.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that

the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-6 and 22-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6660296 ('296). The relevant portions of '296 are given above. In addition, '296 teaches that diltiazem may be administered in tablet form (see col 1, lines 13-19).

'296 fails to teach forming a molded product from the granulated product.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to tablet the diltiazem granules of '296 to afford a tablet (a molded product). '296 teaches that tablets are an appropriate dosage form for diltiazem, and by tableting the granules of '296, an appropriate dosage form for delivering diltiazem will be made. This tablet, which would be made of sustained release diltiazem granules, will provide sustained release of the drug.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number

is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

September 5, 2009